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Perspective

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Reviewing the Safety of our Foods and Drugs: An Urgent Need for a Comprehensive Reevaluation by FDA of Talc in The American Food and Drug Supply

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Introduction

Over the past year, the chronic disease epidemic has become a central focus in national health discussions. Today, over 60% of Americans are living with some form of chronic disease, and nearly 40% are affected by multiple conditions, including cancer and chronic inflammatory conditions. This staggering reality underscores the urgent need to address the underlying causes of this generational crisis in American public health.

One crucial step in understanding the causes of the chronic disease epidemic is to comprehensively reevaluate the safety of the foods and drugs consumed by Americans, particularly regarding additives. Many substances that have been used for decades have not undergone proper scrutiny to assess their long-term health impacts. For example, the Food and Drug Administration's (FDA) GRAS (Generally Recognized as Safe) list includes substances that have not been reviewed for their safety in over 50 years, despite the emergence of new data and information. Under the GRAS designation, substances can be exempted from premarket review if deemed safe by qualified experts for their intended use. With hundreds of substances on this list and no significant scientific review conducted in decades, the current status of allowed food additives relies on outdated data. Furthermore, this list does not take into account the substantial changes in the American population over recent decades. Therefore, a complete overhaul of the review and categorization process for substances currently used as additives in our foods and drugs is essential.

In March 2025, Secretary of Health and Human Services (HHS) Robert F. Kennedy, Jr. made it clear that he seeks to eliminate this loophole, aiming to improve transparency and enhance food safety nationwide. It remains unclear which

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substances will be prioritized and how they will be reevaluated. We have begun a systematic review of the safety of substances commonly used in our foods and drugs. This perspective outlines our findings on one such substance: talc.

Talc: A Ubiquitous Additive in the American Food Supply

One of the substances that has been on the GRAS list and assumed to be safe since the late 1970s is talc, a naturally occurring soft mineral composed of magnesium, silicon, and oxygen that was first discovered in the early 19th century.[1] While it is mined throughout the world, the current supply is derived mainly from China. In nature, talc deposits are often found in proximity to or intermixed with asbestos, a well-known carcinogen. This close association led to early talc products being contaminated with asbestos. However, significant efforts in the 1970s aimed to produce talc that was largely free of asbestos. Since then, talc has typically been manufactured in a form that is generally asbestos-free. However, in December 2024, the FDA mandated the use of more sensitive analytical methods for the screening of asbestos in talc for cosmetics. Curiously, the FDA did not mention the use of these methods for the monitoring of talc for foods and drugs.

Talc's abundance, as well as its absorbent and lubricant properties, make it a common ingredient in baby powder, cosmetics, and some of the most commonly prescribed pharmaceuticals,[1] in which it is used as a lubricant to facilitate pill manufacturing. Table 1 summarizes the prevalence of talc-based pills in the United States.

Table 1: Prevelance of talc-based pills in the United States

Drug Name	US Rank*	Annual Prescriptions**	Annual Patients**
Lipitor	1	39,230,623	10,000,981
Synthroid	3	16,667,810	4,103,489
Prilosec	9	10,387,902	2,965,153
Neurontin	10	4,014,148	988,954

*ClinCalc Database including brand and generic

**Calculated using the percentage brand of total from company annual reports and Growth Plus Reports
In addition to the medications listed in Table 1, proton pump inhibitors Nexium OTC and Prilosec's OTC (common treatments for GERD) both also contain talc. These medications as well as Synthroid, all containing talc, are associated with increased cancer risk in humans.[2,3]

Talc is also a texturizing, anti-sticking agent. Beyond its use in cosmetic and medical products, it is used in virtually all kinds of flavored chewing gum,[4] candy, as well as many kinds of commonly consumed OTC supplement pill tablets.[5] It's no surprise that as of 2019, the total consumption of talc in the United States was 640 thousand metric tons[6] (most of it mined and supplied by China, where there are reports that talc powder is systemically added to wheat flour across the country[7]). Moreover, the WHO Food Standards database CODEX-a list of common food and additive combinations-reports over 50 everyday foods that may contain talc.

Talc Toxicity

In 1993, the National Toxicology Program (NTP) led a talc inhalation study, which found "clear evidence of carcinogenic activity" of talc in female mice, specifically leading to ovarian cancer.[8] This pivotal finding spurred numerous epidemiological and population-based studies aimed at further investigating the connection between talc use and cancer.

A comprehensive review of studies conducted between 1990 and 2013 found a relative ovarian cancer risk of 1.3 with prolonged talc use, indicating an increased

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risk associated with long-term exposure.[9] In 2019, a review of 30 epidemiological studies found a similar relative risk of 1.28 with perineal talc use,[10] further strengthening the association. Additionally, a large retrospective study involving one million patients in Taiwan found a positive association between the oral intake of talc (without asbestos) and an increased risk of stomach cancer, adding another layer to the growing concerns about talc's carcinogenic potential.[11]

The World Health Organization's International Agency for Research on Cancer (IARC) took similar findings seriously and assembled a working group of 29 international experts to examine the carcinogenicity of talc.[12] Examining experimental animal studies, IARC concluded that there is strong evidence of carcinogenic activity in humans associated with talc use. The group emphasized the "strong mechanistic evidence" that talc exhibits key characteristics of carcinogens in human primary cells and experimental systems. Evidence includes the increased incidence of alveolar/bronchiolar adenoma and carcinoma in talc-exposed female rats, as well as granulomatous inflammation in nearly all rats exposed to talc.[8] Subsequent studies have repeatedly shown that talc is a potent inflammatory agent, capable of inducing long-lasting and severe inflammation, including granuloma formation and tissue damage,[13] especially in the context of pleurodesis (a procedure that involves talc exposure)[14].

At the molecular level, talc exposure has been shown to increase the production of reactive oxidative species, compromising the immunosurveillance functions of macrophages and contributing to carcinogenic activity.[15] Furthermore, talc exposure induces specific point mutations in redox enzymes, leading to an imbalance between prooxidants and antioxidants, which fosters the growth of epithelial ovarian cancer cells.[16]

Given the overwhelming body of scientific evidence linking talc to cancer, foreign regulatory bodies are taking action. The European Union, for instance, is set to ban talc in cosmetics by 2027.[17] In September 2024, the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) published a report that reviewed the latest literature on the subject. The committee concluded that there is sufficient evidence to support the assertion that talc can induce tumors in different species and at various sites, citing evidence of lung tumors in female rats and ovarian tumors in women. The RAC determined that the mechanism for tumor development in both lung and ovarian tissues is "biologically plausible," supporting the combined evidence of talc's carcinogenicity.

A Serious Need for Reevaluation

As evidence mounts about the potential carcinogenic risks of talc, the legal landscape surrounding the substance has become increasingly contentious. Johnson & Johnson (J&J), using talc in some of its best-selling cosmetic and consumer products, has faced numerous lawsuits in recent years that have made national headlines. Most recently, J&J has been scrambling to defend a proposal to resolve over 60,000 claims through the bankruptcy of a subsidiary, amounting to a staggering $10 billion. In one notable case, Ingham v. Johnson & Johnson (2020), a Missouri appellate court upheld a $550 million judgment for plaintiffs who claimed J&J's talc products caused cancer. Each plaintiff was awarded $25 million in actual damages, with an additional $4.14 billion in punitive damages.[18]

The recent legal fallout and public outcry from these cases underscore the urgency with which federal health agencies must reevaluate talc's status as a safe additive. As scientific studies continue to reveal the carcinogenic and pro-inflammatory potential of talc, and with regulatory bodies like the European Union moving to ban talc by 2027, the public health establishment's continued inaction becomes increasingly indefensible. Relevant agencies must take immediate steps to address the growing body of evidence and safeguard public health. Especially following the HHS' recent communications about GRAS substances, we call for the federal health agencies to prioritize a thorough and transparent reevaluation of talc's risks,

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including its widespread presence in everyday products like food, cosmetics, and pharmaceuticals. The health of millions of people may depend on it.

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